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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/938,819	LEMMENS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maureen M. Wallenhorst	1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the application filed on August 27, 2001.
2. ☒ The allowed claim(s) is/are 1-16.
3. ☒ The drawings filed on 27 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                     | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|  | 9. <input type="checkbox"/> Other _____.  |

Maureen M. Wallenhorst  
 Primary Examiner  
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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Buscher on March 18, 2004.

On lines 4-5 of page 1 in the specification, the phrase "co-pending" was deleted. On line 5 of page 1, the phrase --now abandoned, -- was inserted after the phrase "filed March 16, 2001," so as to update the status of the parent application.

On line 2 of claim 2, the phrase "the solvent" was changed to --a solvent--. On line 3 of claim 2, the word --of-- was inserted after the word "amount". On line 4 of claim 2, the phrase "the chromatograph" was changed to --a chromatographic plate--. On line 5 of claim 2, the phrase --produced on a chromatogram-- was inserted after the word "spot".

On line 1 of claim 3, the abbreviation "HPLC" was changed to --high performance liquid chromatography (HPLC)--. On line 2 of claim 3, the phrase "the solvent" was changed to --a solvent--. On line 3 of claim 3, the word --of-- was inserted after the word "amount". On line 4 of claim 3, the phrase "the chromatograph" was changed to --a chromatographic column--. On lines 4-5 of claim 3, the phrase "the resolution factor" was changed to --a resolution factor--. On line 5 of claim 3, the phrase "the response factor" was changed to --a response factor--. On the last line of claim 3 before the period, the phrase --on a chromatogram-- was inserted.

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On line 1 of claim 7, the phrase –in a sample containing amlodipine maleate—was inserted after the word “impurity”. On line 7 of claim 7, the abbreviation –(TLC)—was inserted after the phrase “thin layer chromatography”. On line 10 of claim 7, the phrase “the reference marker” was changed to –amlodipine aspartate or amlodipine maleamide--.

On line 1 of claim 8, the phrase –in a sample containing amlodipine maleate—was inserted after the word “impurity”. On line 7 of claim 8, the abbreviation “HPLC” was changed to –high performance liquid chromatography (HPLC)--. On line 8 of claim 8, the phrase “each solution” was changed to –each sample and reference solution on a chromatogram--.

On line 2 of claim 11, the abbreviation “HPLC” was changed to –high performance liquid chromatography (HPLC)--.

On line 8 of claim 12, the word “and” at the end of the line was deleted. On line 11 of claim 12, the phrase –in said sample—was inserted after the word “maleate”. On line 13 of claim 12, the phrase –in said sample—was inserted after the phrase “maleamide”.

On line 1 of claim 16, the word “not” was deleted. On line 2 of claim 16, the phrase –in said sample—was inserted after the word “maleamide”.

2. The following is an examiner’s statement of reasons for allowance: Application serial no. 09/938,819 is being allowed since none of the prior art of record teaches or fairly suggests that amlodipine aspartate and amlodipine maleamide are impurities in pharmaceutical dosage forms of amlodipine maleate, and therefore, none of the prior art of record teaches or fairly suggests using amlodipine aspartate and amlodipine maleamide as reference markers for testing the purity or stability of a sample of amlodipine maleate, separating amlodipine maleate from either amlodipine aspartate or amlodipine maleamide, and analyzing the amount of amlodipine

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aspartate and amlodipine maleamide in a pharmaceutical dosage form of amlodipine maleate to determine whether or not to sell or release the pharmaceutical dosage form into the marketplace.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

March 18, 2004

*Maureen M. Wallenhorst*  
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